SUPREME COURT, U. S.
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No. 39

Supreme Court of the United States

OCTOBER TERM, 1966

ABBOTT LABORATORIES, ET AL., *Petitioners,*

v.

JOHN W. GARDNER, Secretary of Health, Education and Welfare, and JAMES L. GODDARD, Commissioner of Food and Drugs, *Respondents.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR PETITIONERS

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR PETITIONERS

This case is before the Court on writ of certiorari (383 U. S. 924) to review judgments of the United States Court of Appeals for the Third Circuit.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Third Circuit in its case No. 15055 (R. 66-74) is reported at 352 F. 2d 286. The Court of Appeals' opinion in its case No. 15054 (R. 64-65) is reported at 352 F. 2d 524.

The opinion of the United States District Court for the District of Delaware (R. 41-55) is reported at 228 F. Supp. 855.

JURISDICTION

The judgments of the Court of Appeals were entered on November 1, 1965 (R. 65, 74-75). The petition for writ of certiorari was filed on December 15, 1965, and the petition was granted on February 28, 1966 (383 U. S. 924; R. 75). The jurisdiction of this Court is invoked under 28 U. S. C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

The pertinent provisions of the Declaratory Judgment Act (28 U. S. C. §§ 2201-02), Section 10 of the Administrative Procedure Act (60 Stat. 243 (1946), 5 U. S. C. § 1009), Section 1391 of the Judicial Code (28 U. S. C. § 1391), Sections 502(e), 502(n), and 701 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1050, 1055 (1938), 76 Stat. 791 (1962), as amended, 21 U. S. C. §§ 352(e), 352(n), 371), and Sections 1.104(g) and 1.105(b) of the Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act (28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b)) are set forth in the Appendix to this Brief.

QUESTIONS PRESENTED

1. Whether a controversy appropriate for judicial determination, under the Declaratory Judgment Act and the Administrative Procedure Act, as to the validity of formal administrative regulations is presented on the complaint of companies subject to the regulations, (a) where compliance with the regulations will cause these companies grave and irreparable injury, (b) where noncompliance will render the companies subject to civil and criminal prosecutions, seizure proceedings, and harmful administrative actions, and (c) where the validity of the regulations presents a clear-cut issue of statutory construction admittedly without disputed factual questions.

2. Whether, under 28 U. S. C. § 1391(e), the statute recently enacted to liberalize venue requirements in actions against Federal officials, certain corporate petitioners are residents of and entitled to sue in a Federal District Court in a state other than the state of their incorporation.

STATEMENT

Proceedings below

Petitioners are thirty-seven companies that manufacture and distribute prescription drugs and the Pharmaceutical Manufacturers Association ("PMA"), an association of which these companies and other prescription drug companies are members (R. 4-7). Petitioners instituted this action in the United States District Court for the District of Delaware for a declaration that certain regulations issued by the respondents, the Secretary of Health, Education and Welfare and the Commissioner of Food and Drugs, are invalid and for an injunction against the regulations' enforcement (R. 16-17). The District Court's jurisdiction was invoked under Sections 1331 and 1337 of the Judicial Code, 28 U. S. C. §§ 1331, 1337, the Declaratory Judgment Act, and Section 10 of the Administrative Procedure Act (R. 4).

Respondents moved to dismiss on jurisdictional and procedural grounds and for summary judgment if the merits should be reached (R. 18-21). Petitioners filed a cross-motion for summary judgment (R. 22-23). The case was heard on these motions. No answer was filed. No affidavits were filed by the respondents disputing any of the factual allegations in the Complaint.

Of the thirty-eight petitioners, there were twelve—PMA, a Delaware nonprofit membership corporation, and eleven individual companies incorporated in Delaware (see R. 4-7)—as to which venue was not challenged and was

clearly proper. The District Court held that a justiciable controversy was presented and rejected other jurisdictional arguments which respondents interposed as obstacles to an adjudication on the merits. Having reached the merits, the District Court held the regulations invalid on the ground that they were inconsistent with the governing statute and enjoined enforcement of the regulations (R. 62-63).

Respondents appealed to the United States Court of Appeals for the Third Circuit (case No. 15055). The Court concluded that the District Court should have dismissed the action and reversed. It held that review of the regulations was not available "in view of the policy of Congress limiting prior judicial review of administrative actions under . . . [the Food, Drug, and Cosmetic] Act to specific sections, not including the ones in question, and in view of the absence of an 'actual case or controversy' required for justiciability under the Declaratory Judgment Act" (R. 74). The Court of Appeals did not deal with the question of the validity of the challenged regulations.

The District Court, while it reached the merits of the controversy and held the regulations invalid, had dismissed from the action those petitioners not incorporated in Delaware, holding that venue was not proper as to such petitioners. These petitioners appealed from this venue ruling, and in case No. 15054 the Court of Appeals affirmed this aspect of the District Court's decision.

The Court of Appeals has stayed the issuance of its mandate in both cases.

Nature and effect of the regulations

In 1962, the Federal Food, Drug, and Cosmetic Act was amended to provide, in Section 502(e)(1)(B), that a prescription drug is deemed "misbranded" unless the

"established name"[1] of the drug on the drug's label or labeling

> "is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug. . . ."

Section 502(n) of the Act, added in 1962, imposes the same requirement for advertisements of prescription drugs (Appendix, p. 4a).

On June 20, 1963, regulations relating to these statutory provisions were adopted by the respondents. The regulations were issued after a formal rule-making proceeding in accordance with Section 4 of the Administrative Procedure Act, 60 Stat. 238 (1946), 5 U. S. C. § 1003,[2] and were published in the Federal Register, 28 Fed. Reg. 6375. They were entitled "Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act." *Ibid.* They were made effective upon their publication. *Id.* at 6377.

Section 1.104(g) of the regulations, in contrast to the statutory requirement, ordered that the established name of a prescription drug "shall accompany each appearance" of that drug's proprietary or brand name on "labels"

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[1]The established name of a drug is defined in § 502(e)(2) of the Act, added by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(2). Under that section, the established name of a drug may be a "common or usual name," an "official title" used in an "official compendium," or an "official name" designated by the Secretary under § 508 of the Act, added by § 111(a) of the Drug Amendments of 1962, 76 Stat. 789, 21 U. S. C. § 358.

[2]Proposed regulations were published on February 14, 1963, 28 Fed. Reg. 1448. In response, the petitioning companies, either individually or through PMA, submitted comments contending, *inter alia*, that respondents could not lawfully impose the requirement contained in the proposed regulations that is the subject of this action (R. 13). Petitioners' contention was rejected by the respondents when the final regulations were issued.

and "labeling" for the drug. (Appendix, p. 7a). This same "every time" requirement was imposed for advertisements of prescription drugs by Section 1.105(b) of the regulations. (Appendix, p. 7a). These regulations were made applicable to advertisements and, by reason of the expansive definition of "label" and "labeling" in the Act,[8] to every piece of printed matter relating to a prescription drug—to "brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, house organs, literature reprints, and similar pieces of printed matter." Section 1.105(l), 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(l). The "every time" requirement imposed by the regulations applies both to one-page advertisements in medical journals and to books up to 100 pages or more which comprehensively set forth full information as to prescription drugs. It applies no matter how many times the brand name of a drug is mentioned in any single item or, indeed, on any single line or page. Each time the brand name of a drug appears on any of these items, the regulations require that its established name be printed in juxtaposition.

The regulations had a direct impact on each company involved in this litigation. In the regular course of business each company affixes labels to its prescription drugs and distributes labeling and advertising material in connection with these drugs (R. 8). Each company generally employs a proprietary (brand) name with respect to each prescription drug which it distributes, and these brand names appear on printed matter (including labels, labeling, and advertising) relating to the particular prescription drug

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[8] "Label" is defined in § 201(k) of the Act, 52 Stat. 1041 (1938), 21 U. S. C. § 321(k), as "a display of written, printed, or graphic matter upon the immediate container of any article. . . ." Under § 201(m), "labeling" means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

(R. 10). This printed matter is subject to the "every time" requirement imposed by the regulations.

Compliance with these mandatory regulations would require each company to cease the distribution of printed matter which did not contain an "every time" mention of the established name, to destroy such existing materials and to prepare new materials in their place that would be more difficult to read and comprehend and would in this and other ways injure the company's business (R. 15-16). Under Sections 302-04 of the Act, 52 Stat. 1043 (1938), as amended, 21 U. S. C. §§ 332-34, noncompliance with the regulations subjects each company to seizure proceedings, under which valuable drugs can be forfeited, and to criminal prosecutions and injunction proceedings (R. 11-12).[4] Respondents can also indirectly enforce the regulations by refusing to approve the marketing of "new drugs" under Section 505 of the Act, 52 Stat. 1052 (1938), as amended, 21 U. S. C. § 355, and by refusing to certify each batch of antibiotics under Section 507 of the Act, 59 Stat. 463 (1945), as amended, 21 U. S. C. § 357, unless related printed matter complies with the "every time" requirement (see R. 73-74).

During the course of argument in the District Court, it was made clear that respondents intended petitioners to comply with the regulations and that noncompliance would call into play the drastic enforcement provisions of the Act

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[4]Indeed, § 1.105(k) of the regulations, 28 Fed. Reg. 6377, 21 C. F. R. § 1.105(k), provides that any advertisement not in compliance with the "every time" requirement "shall cause stocks of such drug in possession of the person responsible for issuing or causing the issuance of the advertisement . . . to be misbranded under section 502(n) of the act." Sections 301(a) and (b) of the Act, 52 Stat. 1042 (1938), as amended, 21 U. S. C. §§ 331(a), (b), prohibit the "misbranding" of any drug and the introduction into commerce of any "misbranded" drug, and §§ 302-04 of the Act specify the sanctions for violating § 301.

(R. 25). These drastic remedies can be invoked—even though the drugs are perfectly safe and effective and even though the established name appears "prominently" on every page and no doctor or patient could be misled—solely on the ground that the established name does not appear every single time the proprietary name is used, as required by the regulations.

SUMMARY OF ARGUMENT

I

The regulations involved here affect the entire prescription drug industry. They were promulgated in 1963, more than three years ago, and petitioners promptly presented their claim that the regulations went beyond respondents' statutory authority for adjudication by the courts. That the claim has substance is clear from the fact that the District Court, the only court that has considered the question, held the regulations invalid. The Food and Drug Administration ("FDA") was itself on record that it welcomed resolution of this type of question by the courts. Yet in this proceeding, as in a case recently decided by the Court of Appeals for the Second Circuit, *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677,[8] respondents have made every conceivable effort to avoid decisions on the merits of controversies by the Federal courts.

The interests of all concerned—the FDA itself, the prescription drug industry, and the public—would be served by a definitive judicial determination as to the validity of the regulations. The Court of Appeals should have decided this question and should be directed to do so by this Court. There is no reason why petitioners should be required to violate the regulations, be prosecuted, and be prevented

[8] Petitions for writs of certiorari have been filed in this case. Nos. 336, 438, October Term, 1966.

from marketing new drugs and antibiotics before the validity of the regulations can be determined. Nor is there any possible justification for permitting respondents to hold an entire industry at hazard under the regulations by resisting an immediate straightforward test of their validity.

A clear-cut legal question of statutory construction was presented by the cross-motions for summary judgment. No facts were in dispute. No facts bearing on the validity of the regulations would be any different in a future enforcement proceeding from what they are today.

The regulations, once promulgated, were reviewable in this action instituted under the Declaratory Judgment Act and the Administrative Procedure Act. Adopted after a formal rule-making proceeding, they were published in the Federal Register and made effective upon their publication. They were represented to be "enforcement" regulations and were mandatory in nature—commanding that petitioners label and advertise their drugs in a certain way. In order to comply with the regulations, petitioners would have had to change their methods of doing business. On the other hand, noncompliance with the regulations would have exposed petitioners to drastic sanctions, including criminal penalties and seizure proceedings, as well as efforts by the respondents to prevent, through administrative action, the marketing of new and valuable drugs.

Under these circumstances, there was an "actual controversy," appropriate for judicial resolution, within the meaning of the Declaratory Judgment Act. That Act was designed to be available to relieve those subject to overreaching governmental action of the necessity of either complying with that action or suffering severe sanctions to test legality, the precise situation in which petitioners were put when the regulations were promulgated. By reason of the adverse impact of the regulations on petitioners, the regulations

were reviewable in this action, and it was not necessary that enforcement or penal proceedings be instituted before the legality of the regulations could be judicially determined. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956).

The regulations were also reviewable under Section 10 of the Administrative Procedure Act ("APA"). The District Court had jurisdiction over the subject matter of this action and in personam jurisdiction over the respondents, the regulations constituted "final agency action," and petitioners had suffered "legal wrong" as a consequence of that action. *United States* v. *Storer Broadcasting Co., supra.*

The Court of Appeals obviously erred in holding that the regulations were not ripe for review. The principles announced in the leading administrative law decisions of this Court, but ignored by the Court of Appeals, apply in determining the ripeness of regulations for review under the Declaratory Judgment Act and the APA. Under these decisions, it is clear that the regulations at issue here, whether or not characterized as "interpretive," were reviewable in this action. It is also clear that there is no requirement that there must be a specific and explicit threat of enforcement against a particular corporation before the legality of these formal, mandatory regulations can be judicially determined.

There is no basis for the conclusion that Congress intended to preclude judicial review of the regulations at issue here. There is no express preclusion of review in the statute. The mere fact that certain other types of regulations were made reviewable in a specific manner under the Food, Drug, and Cosmetic Act is no indication that Congress intended, as the Court of Appeals held, to preclude resort to traditional equitable and declaratory remedies in the

case of regulations of the type at issue here. See *Shields* v. *Utah Idaho Central R. R.*, 305 U. S. 177 (1938); *Stark* v. *Wickard*, 321 U. S. 288 (1944). There is lacking in this case "clear and convincing evidence" of congressional intent to preclude review. *Rusk* v. *Cort*, 369 U. S. 367 (1962); *Heikkila* v. *Barber*, 345 U. S. 229 (1953). On the contrary, the Act itself and its legislative history demonstrate the lack of any such congressional intent. Indeed, they show that Congress contemplated that traditional remedies would continue to be available to challenge any FDA action. The Act's judicial review provision, Section 701(f), is expressly stated to "be in addition to and not in substitution for any other remedies provided by law." The legislative history shows that Congress took note of the fact that these "other remedies provided by law" could include equity and declaratory judgment proceedings.

In short, the Declaratory Judgment Act and the judicial review provisions of the APA are applicable to the regulations at issue here, and the regulations were ripe for review under these statutes. The case should be remanded to the Court of Appeals for decision on the merits.

II

The Complaint was improperly dismissed as to those petitioners not incorporated in Delaware. Venue in this action against Federal officials is proper not only in the judicial district in which a corporation is incorporated, but also where it is licensed to do business or doing business. The contrary ruling below does not give proper scope to the definition of corporate residence in 28 U. S. C. § 1391(c) and is not in keeping with the purpose of 28 U. S. C. § 1391(e), the provision added in 1962 to liberalize the venue requirements applicable in actions against Federal

officials. While decision either way on this issue does not affect the outcome of this case, the issue should be resolved by the Court to clarify the meaning of these venue provisions and settle conflicting decisions in lower courts.

ARGUMENT

I

THE REGULATIONS ARE REVIEWABLE IN THIS ACTION

This action was brought by the prescription drug industry in order to be relieved of the burden of illegal regulations adopted by respondents. The alternative to this action—and a consequence of the Court of Appeals' decision if not reversed—would be individual enforcement proceedings against companies which do not comply with what the respondents have formally and finally announced as their interpretation of the statute. *Cf. National Van Lines, Inc.* v. *United States,* 326 F. 2d 362, 373 (7th Cir. 1964). This type of piecemeal litigation, binding only on the immediate parties to any particular action, would only serve to delay resolution of the basic question of whether the industry must comply with the regulations, a question whose prompt determination is in the public interest as well as in the interest of those subject to the regulations. Professor Jaffe is certainly correct when he observes:

> "The public has an interest in early implementation of policy; the regulated person has a legitimate interest whether to plan or not to plan his operation on the basis of a regulation." Jaffe, *Judicial Control of Administrative Action* 404 (1965).

The Food and Drug Administration itself has recognized the desirability of judicial proceedings instituted in good faith to challenge the legality of FDA regulations:

> "When any interested party feels that one of our regulations is wrong and should be challenged in the courts, we welcome such an action. Court decisions interpreting sections of the law or regulation that have given rise to honest differences of opinion are most helpful to us as guidelines to fair administration." Address of Commissioner of Food and Drugs George P. Larrick before the Pharmaceutical Manufacturers Association, April 14, 1964, p. 4.

From petitioners' standpoint, the desirability—indeed, the necessity—of obtaining a prompt determination of the regulations' validity is equally clear. Respondents did not controvert the adverse impact of the regulations on the petitioners. There is no dispute that compliance with the regulations requires petitioners to discontinue distributing the form of promotional material they have previously distributed, including such material now in their possession, and to substitute material they otherwise would not use. In effect, in order to comply, a change in petitioners' methods of doing business would be required. Nor is there any dispute that, under the statute, noncompliance with the regulations would render petitioners subject to criminal prosecutions, seizure actions, and injunction proceedings, as well as to administrative enforcement of the regulations through efforts to prevent the initial marketing of drugs and antibiotics whose printed matter does not comply with the regulations. As determined by the District Court:

> "The regulations in issue have placed them [petitioners] in a dilemma. Either they must comply with the every time requirement and incur the costs of changing over their promotional material and labeling or they must follow their present course and risk prosecution." (R. 49).

Finally, the issue of the regulations' validity is an issue that was particularly appropriate for resolution in this

action. It is a clear-cut legal issue of statutory construction. It was tendered on cross-motions for summary judgment presenting no disputed factual questions.

Under these circumstances, petitioners should not be forced to the choice of either complying with regulations believed to be unlawful—a belief shared by the District Court—or running the risk of suffering severe sanctions. Respondents should not be permitted to hold an entire industry at hazard, arbitrarily selecting the companies against which these sanctions will be invoked and the drugs whose marketing will be delayed. There is no reason for not having, once and for all, a final determination of the validity of the regulations in this action. There existed with respect to the regulations an "actual controversy," appropriate for judicial resolution, within the meaning of the Declaratory Judgment Act. In addition, the regulations constituted "final agency action" within the meaning of the APA, and declaratory and injunctive relief was appropriate under that Act.

The Court of Appeals, however, determined (1) that no justiciable controversy was presented and (2) that review of these regulations was not available under the Declaratory Judgment Act and the APA because only other types of FDA action are made expressly reviewable under the Food, Drug, and Cosmetic Act. Both of these grounds of the Court of Appeals' decision have been specifically rejected by the Second Circuit in a persuasive and well-reasoned opinion of Judge Friendly, *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677 (2d Cir. 1966). They should also be rejected by this Court. As the Second Circuit held with respect to the availability of the Declaratory Judgment Act and the APA:

> "We are not persuaded that by providing a procedure for review of certain administrative decisions under the Food and Drug Act in the courts of

> appeals, Congress meant to foreclose relief with respect to other agency action under the Administrative Procedure Act § 10, 5 U. S. C. § 1009, or the Declaratory Judgment Act, 28 U. S. C. § 2201, in a case where this would otherwise be appropriate. . . . Insofar as Abbott Labs. v. Celebrezze, 352 F. 2d 286, 289 (3 Cir. 1965), cert. granted, intimates otherwise, we are unwilling to follow it." 360 F. 2d at 683-84.

And, on the issue of justiciability:

> "Agreeing with the defendants that Abbott Labs. v. Celebrezze, 352 F. 2d 286 (3 Cir. 1965), cert. granted, is not distinguishable on any satisfying basis, we must confess, with all respect, our inability to understand why the plaintiffs there should be required to violate the challenged FDA regulation in order to raise the same legal issue as to which the district court had granted declaratory relief." 360 F. 2d at 686-87.

A. The Regulations Are Reviewable Under the Declaratory Judgment Act

At the outset, it deserves emphasis that a challenge to administrative regulations under the Declaratory Judgment Act is not a matter that is foreign to the purpose of that Act; the Act was specifically designed to be available not only in the area of private disputes but also in situations where the validity of governmental action is controverted. As explained in the 1934 Senate Judiciary Committee Report:

> "The [declaratory judgment] procedure has been especially useful in avoiding the necessity, now so often present, of having to act at one's peril or to act on one's own interpretation of his rights, or abandon one's rights because of a fear of incurring

damages. So now it is often necessary, in the absence of the declaratory judgment procedure, to violate or purport to violate a statute in order to obtain a judicial determination of its meaning or validity. Compare *Shredded Wheat Co.* v. *City of Elgin* (284 Ill. 389, 120 N. E. 248, 1918), where the parties were denied an injunction against the enforcement of a municipal ordinance carrying a penalty, and were advised to purport to violate the statute and then their rights could be determined, with *Erwin Billiard Parlor* v. *Buckner* (156 Tenn. 278, 300 S. W. 565, 1927), where a declaratory judgment under such circumstances was issued and settled the controversy.

* * *

"The Supreme Court mentioned one of its [declaratory judgment procedure] principal purposes in *Terrace* v. *Thompson* [263 U. S. 197, 216 (1923)] . . . : 'They are not obliged to take the risk of prosecution, fines, and imprisonment and loss of property in order to secure an adjudication of their rights.' " S. Rep. No. 1005, 73d Cong., 2d Sess. 2-3, 6 (1934).

Professor Borchard, the principal draftsman and proponent of the Declaratory Judgment Act and "a recognized authority on this subject,"[8] has stated:

"Possibly in no branch of litigation is the declaration more useful than in the relations between the citizen and the administration. With the growing complexity of government, . . . with ever widening

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[8]H. R. Rep. No. 2755, 74th Cong., 2d Sess. 8 (1936). As stated by this House Committee in reporting a previous version of the Food, Drug, and Cosmetic Act:

"The remedy furnished [by the Declaratory Judgment Act] seems to be peculiarly adapted to cases where the interests and rights of parties are affected by the acts of administrative officials." *Ibid.*

> powers vested in administrative boards and officials, the occasions for conflict and dispute are rapidly augmenting in frequency and importance. Yet the very fact that such disputes turn mainly upon questions of law, . . . makes this field of controversy peculiarly susceptible to the expeditious and pacifying ministrations of the declaratory judgment." Borchard, *Challenging 'Penal' Statutes by Declaratory Action*, 52 Yale L. J. 445 (1943).

Of course, in any particular situation the statutory requirement that there be an "actual controversy"—a requirement dictated by the constitutional "case or controversy" requirement[7]—must be satisfied. That this requirement was met in this case is shown by this Court's decisions in the landmark cases dealing with the ripeness of administrative regulations for review. *Columbia Broadcasting System, Inc.* v. *United States*, 316 U. S. 407 (1942); *Frozen Food Express* v. *United States*, 351 U. S. 40 (1956); and *United States* v. *Storer Broadcasting Co.*, 351 U. S. 192 (1956). These cases demonstrate that, because of the adverse impact of the regulations on petitioners, the regulations were reviewable in this action, and petitioners did not have to act at their peril and await the institution of penal or enforcement proceedings before the legality of the regulations could be judicially determined. *Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677, 685-86 (2d Cir. 1966).

Columbia Broadcasting involved FCC regulations which provided that licenses would not thereafter be issued to stations having certain contractual relationships with networks. Although, as the Court noted, the regulations were not self-executing—they "did not operate of their own force to deny or cancel a license," 316 U. S. at 417—the

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[7] See Public Serv. Comm'n v. Wycoff Co., 344 U. S. 237, 242 (1952); United Pub. Workers v. Mitchell, 330 U. S. 75, 89, 93 (1947).

regulations were held to be ripe for review because of their adverse impact on CBS. The regulations purported to set a "standard of conduct," 316 U. S. at 418, and posed "the alternatives of compliance or severe penalties of forfeiture or disruption of business operations." *Toilet Goods Ass'n, supra*, 360 F. 2d at 685. As stated by this Court:

> "It is enough that failure to comply with them [the regulations] penalizes licensees, and appellant, with whom they contract. If an administrative order has that effect it is reviewable and it does not cease to be so merely because it is not certain whether the Commission will institute proceeding to enforce the penalty incurred under its regulations for non-compliance." 316 U. S. at 417-18.

The Court rejected an argument that the regulations were "no more subject to review than a press release similarly announcing . . . policy," 316 U. S. at 422, pointing out that the regulations were "avowedly adopted in the exercise of [rule-making] . . . power, [and were] couched in terms of command. . . ." *Ibid.* Although the validity of the regulations could have been determined in a licensing proceeding, the Court held that this was not the exclusive method of review:

> "Having adopted this order under its rule-making power, the Commission cannot insist that the appellant be relegated to that judicial review which would be exclusive if the rule-making power had never been exercised and consequently had never subjected appellant to the threatened irreparable injury." 316 U. S. at 421.

The *Storer* case also involved a licensing regulation of the FCC that was challenged upon its promulgation. The regulation was held ripe for review because the Commission exercised a power of rulemaking which controls

broadcasters" and the regulations "now operate to control the business affairs of Storer," 351 U. S. at 199, even though, as the dissent pointed out, the regulations could have been reviewed after they had been applied in a licensing proceeding. See 351 U. S. at 208.

In *Frozen Food Express*, this Court again focused on the practical impact of administrative action as the determinative factor in deciding whether such action is ripe for review. *Frozen Food Express* involved an interpretive report of the ICC in which it rendered its opinion as to the status of certain commodities under an exemption provided by the Interstate Commerce Act for the carriage of agricultural products by motor carriers. Over the contention that the report was not reviewable because it "has no operative effect," 351 U. S. at 46, this Court held that the report was reviewable because of its "immediate and practical impact on carriers":

> "The determination by the Commission that a commodity is not an exempt agricultural product has an immediate and practical impact on carriers who are transporting the commodities. . . . The 'order' of the Commission warns every carrier, who does not have authority from the Commission to transport those commodities, that it does so at the risk of incurring criminal penalties. . . . Where unauthorized operations occur, the Commission may proceed administratively and issue a cease and desist order. . . . The determination made by the Commission is not therefore abstract, theoretical, or academic. . . . The 'order' of the Commission . . . is, indeed, the basis for carriers in ordering and arranging their affairs. . . . The 'order' of the Commission is in substance a 'declaratory' one . . . which touches vital interests of carriers . . . and sets the standard for shaping the manner in which an important segment of the trucking business will be done." 351 U. S. at 43-44.

The instant case is "on all fours" with *Columbia Broadcasting, Storer,* and *Frozen Food Express.* Here, as in *Columbia Broadcasting,* an agency exercised its rule-making power to adopt formal, mandatory regulations—regulations "couched in terms of command," 316 U. S. at 422—which had an adverse impact on petitioners. Here, as in *Storer,* the promulgated regulations "operate to control the business affairs of" petitioners. 351 U. S. at 199. Finally, *Frozen Food Express* demonstrates that there is nothing abstract, theoretical, or academic about the controversy presented by the regulations at issue here. As in *Frozen Food Express,* the very existence of the regulations "has an immediate and practical impact on" petitioners. 351 U. S. at 44. Compliance with the regulations requires petitioners to change their method of doing business. On the other hand, noncompliance with the "every time" requirement imposed by the regulations subjects petitioners to the risk of criminal penalties, seizure proceedings, and injunction actions as well as to months of delay in securing the necessary approvals to market new and valuable drugs.[8] The holdings of this Court in these three cases show that an "actual controversy" is presented in this case.

[8] Petitioners recognize that, in the Brief in Opposition to the Petition for Certiorari in this case, the Solicitor General represented (pp. 5-6) that criminal prosecutions will not be brought under the regulations until their validity has been authoritatively determined. Even on the assumption, however, that the Government may be barred from bringing criminal proceedings by statements in a brief, the other severe sanctions which can be invoked for noncompliance with the regulations suffice to demonstrate their reviewability. See *Columbia Broadcasting* and *Storer* in which regulations were held reviewable even though there was no criminal sanction for their violation, and the regulations by their terms were enforceable only by administrative action. In any event, it is clear that the Solicitor General's representation—more than two years after the Complaint was filed—cannot operate to destroy the jurisdiction which the District Court had when the action was instituted or to sustain the Court of Appeals' erroneous dismissal of the action. See American Life Ins. Co. v. Stewart, 300 U. S. 203, 215 (1937); Spector Motor Service, Inc. v. O'Connor, 340 U. S. 602, 605 (1951).

B. The Regulations Are Reviewable Under the Administrative Procedure Act

This action was properly brought under Section 10 of the APA. Section 10 provides for judicial review of "final agency action" by any person suffering "legal wrong" as a result of such action. Section 10(b) contemplates that such review may be obtained through declaratory judgment and injunction actions, such as that brought here, instituted in a "court of competent jurisdiction." (Appendix, pp. 1a-2a).

First, there is no dispute that the District Court was a "court of competent jurisdiction." It had jurisdiction over the subject matter of this action under 28 U. S. C. §§ 1331, 1337 (*cf. Toilet Goods Ass'n* v. *Gardner*, 360 F. 2d 677, 679 (2d Cir. 1966), citing *Smith* v. *Kansas City Title & Trust Co.*, 255 U. S. 180 (1921)), and, through valid service of process under 28 U. S. C. § 1391(e), had acquired in personam jurisdiction over the respondents.

Second, it is also clear, despite the contrary implication in the Court of Appeals' opinion (R. 70), that the regulations fall within Section 10. The operative words are "final agency action." That the regulations constituted "agency action" is evident from the definitions contained in the APA itself,[9] and the *Storer* case demonstrates that the regulations had the requisite "finality." As has been discussed, *Storer* was a case in which regulations were challenged upon their promulgation and, although a specific statutory review provision was involved in that case, the

[9]Each respondent is an "agency" as that term is defined in § 2(a) of the APA, 5 U. S. C. § 1001(a). "Agency action" is defined in § 2(g), 5 U. S. C. § 1001(g), as including "every agency rule," and "rule" is defined in § 2(c), 5 U. S. C. § 1001(c), as "any agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy," a definition that clearly encompasses the regulations at issue in this proceeding.

action was also brought under the APA. See 351 U. S. at 195. The Court held that the regulations constituted "final agency action" within the meaning of the APA:

> "We think [Storer] . . . had standing to sue at the time it exercised its privilege. The process of rule-making was complete. It was final agency action, 5 U. S. C. § 1001(c) and (g): . . ." 351 U. S. at 198.

The regulations involved in this action were also formally promulgated after a completed rule-making proceeding and similarly constitute "final agency action."

Finally, that petitioners suffered "legal wrong" as a consequence of the regulations is also apparent. This requirement was explained as follows in *Storer*:

> "Legal wrong, as a ground for standing to appeal, was introduced by the Administrative Procedure Act. . . . In explanation the reports of the Senate, No. 752, 79th Cong., 1st Sess. 26, and the House, No. 1980, 79th Cong., 2d Sess. 42, define 'legal wrong':
>
> 'The phrase "legal wrong" means such a wrong as is specified in section 10(e). It means that something more than mere adverse personal effect must be shown in order to prevail—that is, that the adverse effect must be an illegal effect.'" 351 U. S. at 197 n. 6.

Section 10(e) of the APA, referred to by the Court, specifies the grounds upon which agency action can be invalidated, grounds specifically relied upon by the petitioners. (Compare Appendix, p. 2a, with R. 14.) In light of *Storer* and Section 10(e) of the APA, therefore, petitioners had suffered "legal wrong" since the "adverse effect" was caused by illegal action of the respondents. It has already been shown, p. 20, *supra*, that in terms of the "adverse effect" of the regulations upon petitioners, this case

is basically the same as *Storer* and the other administrative law decisions of this Court.

In sum, petitioners—persons suffering "legal wrong" as a consequence of the "final agency action" involved in this case—were entitled to review of that action under the Administrative Procedure Act. See *Rusk* v. *Cort*, 369 U. S. 367 (1962); *Brownell* v. *Tom We Shung*, 352 U. S. 180 (1956); *Shaughnessy* v. *Pedreiro*, 349 U. S. 48 (1955), in each of which this Court held that administrative action not reviewable under the statute pursuant to which the action was taken was reviewable under the APA through declaratory judgment and injunction actions.

C. The Court of Appeals Erred in Determining That No Justiciable Controversy Is Presented

What has already been said demonstrates that the Court of Appeals erred in holding that the regulations were not ripe for review. It is, however, appropriate to focus on three specific errors of the Court of Appeals: its refusal to follow the controlling decisions of this Court; its mistaken impression that "interpretive" regulations are ipso facto unreviewable; and its unwarranted assumption that there must be a specific and explicit threat of enforcement against a particular corporation before the validity of regulations may be judicially determined.

1. It ignored decisions of this Court

The Court of Appeals refused to follow *Frozen Food Express* and the other controlling decisions of this Court. Although it did not even mention the *Storer* case, the Court of Appeals sought to distinguish *Columbia Broadcasting* and *Frozen Food Express* on the ground that these cases arose under specific statutory review provisions and were not declaratory judgment actions (R. 69).[10] This distinction

[10] In fact, however, both *Frozen Food Express* and *Storer* were actions brought under the Administrative Procedure Act, as well as under the specific statutory provisions applicable to the ICC and FCC, respectively. See 351 U. S. at 42; 351 U. S. at 195.

has no bearing on the question of ripeness, as the Court of Appeals attempts to argue, for this Court has established that the rules governing justiciability are the same whether suit is brought under specific review provisions or the Declaratory Judgment Act.

Nukk v. *Shaughnessy*, 350 U. S. 869 (1955), *reversing per curiam* 125 F. Supp. 498 (S. D. N. Y. 1954), was a declaratory judgment action brought to challenge the validity of administrative regulations, the same type of action as that involved here. The District Court held, as did the Court of Appeals here, that the regulations were not ripe for review because there had been no specific threat to enforce the regulations. This Court reversed per curiam, saying only:

> "The Court is of opinion that the complaints do present a case and controversy. *Rochester Telephone Corp.* v. *United States*, 307 U. S. 125. The judgment is reversed and the case is remanded for consideration on the merits." 350 U. S. at 869.

Rochester Telephone, although an action brought under a specific statutory review provision, was thus held dispositive in a declaratory judgment action.

The *Nukk* case, in which this Court thought the appropriate decision so clear that it need not even write a full opinion, is of course in accord with decisions of the Court in which it has spelled out its reasoning. The results reached in *Columbia Broadcasting*, *Storer*, and *Frozen Food Express* show that a challenge to a regulation that has an adverse effect on private parties produces a "case or controversy" in the constitutional sense; otherwise, despite the statutory review provisions, each of those cases should have been dismissed for lack of jurisdiction. Since the require-

ment under the Declaratory Judgment Act that there be an "actual controversy" has the same meaning as the constitutional "case or controversy" requirement, see cases cited n. 7, *supra,* the Court of Appeals was clearly in error in holding that the leading administrative law decisions of this Court have no bearing on declaratory judgment actions brought to challenge administrative regulations.[11]

At the risk of belaboring the obvious, it should be pointed out that Professors Jaffe and Davis, two noted students of administrative law, have independently recognized the applicability to declaratory judgment actions of the principles announced in cases brought under specific review provisions. Jaffe, *Judicial Control of Administrative Action* 408 (1965); 3 Davis, *Administrative Law* § 21.06, at 150-51 (1958). In the words of Professor Davis:

> "In many cases, regulations of the ICC and of the FCC have been challenged by suits for injunctions

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[11]This Court's decisions in Ewing v. Mytinger & Casselberry, Inc., 339 U. S. 594 (1950), and Whitney Nat'l Bank v. Bank of New Orleans, 379 U. S. 411 (1965), relied on by the Court of Appeals (R. 70-71), do not affect the *Columbia Broadcasting* line of cases which govern this action. *Ewing* involved an attempt to review a finding of probable cause, not a final regulation. *Whitney Nat'l Bank* rested on the fact that the appropriate agency had never passed upon the contentions urged in the courts; here, petitioners' position as to the illegality of the "every time" requirement had been presented to and rejected by the respondents before this action was filed in the District Court. See n. 2, *supra.*

The Court of Appeals' reliance (R. 70) on the provision in § 502(e)(1)(B) for exemptions from the requirements of that section where compliance would be "impracticable" was also misplaced, for in *Storer* this Court held a regulation reviewable even though the FCC could waive its requirements. See 351 U. S. at 205. Furthermore, the exemption provision applies only to the section of the regulations dealing with labels and labeling and not to the section dealing with advertising, and, finally, petitioners' contention is that the regulations, whether or not compliance would be "practicable," are invalid.

under the Urgent Deficiencies Act; if a suit under that Act is not premature, no reason is apparent for holding premature an ordinary bill in equity or a declaratory action." *Ibid.* (Footnotes omitted.)

2. It sought to minimize the impact of the regulations by labeling them "interpretive"

The majority in *Frozen Food Express* rejected as a touchstone for reviewability the wholly separate question of whether regulations are "interpretive" or "legislative." The Court adopted a pragmatic, realistic approach, focusing on the impact of the regulation on those subject to its terms, and held that the ICC interpretive report involved in that case was ripe for review when it was issued. The Court of Appeals here, however, for some unexplained reason, chose to echo the *dissenting* opinion in *Frozen Food Express.* Compare R. 72 (the regulations do not have the force of law; "they rise no higher than the terms of the Act itself") with 351 U. S. at 46 (dissenting opinion) ("the order has no operative effect"; liability exists "because of a violation of the Act and not the order").

The Court of Appeals thus clearly erred. It is of no significance, as the Court thought, to label regulations "interpretive" (R. 69). As stated by the Court of Appeals for the Second Circuit in *Toilet Goods Ass'n, supra,* 360 F. 2d at 686:

> "[T]he interpretative character of a regulation does not necessarily make it unripe for review; we perceive no reason why a rule whereby an agency subjects to regulation activities contended to be immune should be exempt from immediate review because it purports to interpret a statute although it would not be if made in the exercise, contended to be illegal, of a substantive rule-making power. See Frozen Food Express v. United States . . .; Jaffe,

> Judicial Control of Administrative Action 405-07 (1965); and 1 Davis, Administrative Law Treatise § 5.03 (1965 Pocket Part), criticizing on this ground American President Lines, Ltd. v. FMC, 316 F. 2d 419 (D. C. Cir. 1963). . . ."

See also, *e.g.*, *FCC* v. *American Broadcasting Co.*, 347 U. S. 284 (1954) (immediate review of interpretive regulation); *Amshoff* v. *United States*, 228 F. 2d 261, 265 (7th Cir. 1955), *cert. denied*, 351 U. S. 939 (1956) (interpretive regulation is "final order" and reviewable under the Hobbs Act, 5 U. S. C. § 1032); *Lester C. Newton Trucking Co.* v. *United States*, 209 F. Supp. 600, 602 (D. Del. 1962), *aff'd per curiam*, 372 U. S. 702 (1963) ("interpretive opinion" of ICC held reviewable on authority of *Frozen Food Express*); *De Camp Bus Lines* v. *United States*, 224 F. Supp. 196, 201 (D. N. J. 1963) (order construing carriers' authority under certificate held reviewable). Compare *National Van Lines, Inc.* v. *United States*, 326 F. 2d 362 (7th Cir. 1964) (ICC report declaring that statute had been violated but not imposing sanctions held reviewable on authority of *Frozen Food Express*).

In short, the ripeness of a regulation for review does not depend upon what label is assigned to the regulation. However the regulations at issue here may be categorized, they were ripe for review because of their adverse impact on petitioners.

3. It improperly required a showing that specific enforcement of the regulations against a particular company was contemplated

The Court of Appeals' insistence that there be a specific threat of immediate prosecution (R. 72) is in clear conflict with *Columbia Broadcasting* in which, as noted, p. 18, *supra*, the Court held that regulations were ripe for review

even though it was not "certain" that any enforcement proceedings would be instituted. Nor is there any indication of any official threat of enforcement in *Storer* or *Frozen Food Express.*[12]

It may be that—as held in *Poe* v. *Ullman,* 367 U. S. 497, 508 (1961), with respect to a state statute challenged on constitutional grounds—if those subject to action taken by an administrative agency have no "realistic fear" that the action will be enforced, no justiciable controversy is presented as to the validity of that action. This, however, is clearly not the situation here where the administrative action consists of formally published and purportedly effective regulations, adopted after a rule-making proceeding, which purport to represent the agency's final and considered views, and where these views are stated in mandatory terms. Unless the respondents have been engaging in a purposeless intellectual exercise, how else can the regulations be explained except as incorporating a threat that drugs not complying with the regulations will be proceeded against?

The Complaint alleged that the respondents had a duty to enforce and cause enforcement of the statute in accordance with the regulations (R. 14). This allegation was never controverted. Indeed, respondents' counsel left no doubt during oral argument before the District Court that respondents intended petitioners to comply with the regu-

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[12]Even in cases in which the constitutionality of statutes is challenged in actions to enjoin their enforcement, there is no requirement that there be an official threat or other governmental enforcement action against any particular person who is subject to the statute. In neither Truax v. Raich, 239 U. S. 33 (1915), nor Pierce v. Society of Sisters, 268 U. S. 510 (1925), for example, had there been any such threat or enforcement action when suit was instituted; in each case the impact of the challenged statute upon the plaintiff, coupled with the statute's obvious viability, sufficed to present a justiciable controversy.

lations and that noncompliance would call into play the drastic enforcement provisions of the Act.[13] As the District Court observed, "Surely, the Commissioner does not announce regulations which he does not intend to enforce by any and every lawful means" (R. 49).

Two recent, well-reasoned Circuit Court decisions indicate that the formality of an agency regulation, adopted after notice and the opportunity for the submission of comments, is an important factor bearing on the appropriateness of passing on the validity of the regulation prior to its enforcement.[14] In *Toilet Goods Ass'n*, Judge Friendly, citing this Court's emphasis in *Columbia Broadcasting*, 316 U. S. at 422, and *Storer*, 351 U. S. at 198, on the fact that the agency involved had followed a formal rule-making procedure, stressed that "the Regulations under attack were issued after a full hearing with notice and by their terms represent the definitive agency position. . . ." 360 F. 2d at 685. The same is true of the regulations at issue here.

In addition, the Court of Appeals for the First Circuit, in an opinion by District Judge Caffrey, has stated with respect to the reviewability of a CAB order:

> "The question whether the Board's determination is appropriately reviewable at this point is es-

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[13] "The Court: Mr. Goodrich [counsel for respondents], when your department makes a regulation, I certainly hope that you intend for the drug industry to obey those regulations.

"Mr. Goodrich: We do indeed, sir.

"The Court: If not, you take whatever steps are necessary to enforce them.

"Mr. Goodrich: But the enforcement in the setting of a real case, where we have a piece of promotional material before us, is entirely different from an abstract question which is presented here." (R. 25; see also R. 34-35).

[14] Helco Prods. Co. v. McNutt, 137 F. 2d 681 (D. C. Cir. 1943), relied on heavily by the Court of Appeals here (R. 73), is clearly distinguishable. *Helco* involved an informal, unpublished letter of the FDA, not formal and purportedly final and effective regulations. See Jaffe, *Judicial Control of Administrative Action* 414-15 (1965).

> sentially one of the proper timing of judicial review and of whether this matter involves a sufficiently particularized controversy which is final in the sense that it is an at least firm (and perhaps binding) adoption of a position by the agency with regard to a course of conduct on the part of a member of the regulated industry which does not require further administrative action other than the possible imposition of sanctions. Among the factors to be considered are the relative formality of the agency's position, the degree of potential harm to the petitioner and the relative clarity of the issue presented for review." *Northeast Airlines, Inc.* v. *CAB*, 345 F. 2d 662, 664 (1st Cir. 1965).

The factors set forth by the First Circuit demonstrate the appropriateness of judicial review of the regulations at issue in this case. The regulations were formally adopted, they require a change in petitioners' method of doing business in order to avoid severe sanctions, and the issue presented is a clear-cut legal issue tendered on cross-motions for summary judgment, the basic facts being undisputed. The Court of Appeals' decision that no justiciable controversy was presented is in error.

D. The Court of Appeals Erred in Determining That the Act Precludes Review of the Regulations

Since, as has been shown, a justiciable controversy was presented as to the validity of the regulations, those who would prevent the courts from resolving this controversy must assume a heavy burden. There must be a clear demonstration that, although review would otherwise be proper under the Declaratory Judgment Act or the APA, the Congress intended that these statutes were not to be available to those harmed by this administrative action. There was no such demonstration in this case.

The Court of Appeals purported to find that Congress intended to preclude a judicial determination as to the legality of regulations of the type involved here prior to their enforcement. This determination as to the "intent of Congress" (R. 69, 70) was made even though nowhere in the Food, Drug, and Cosmetic Act is there any express preclusion of review and even though no legislative history was cited to support any such "intent." The Court of Appeals found this preclusionary "intent" solely by reason of the fact that regulations issued under certain sections of the Act, not including those under which the regulations involved here were issued, are made specifically reviewable under the special provisions of Section 701(f) of the Act.

It is clear that the Court of Appeals erred in determining, solely on this basis, that review of these regulations was precluded. First, the Act itself and its legislative history demonstrate that Congress contemplated that declaratory judgment and injunction proceedings would be available to challenge the legality of FDA actions. In addition, this clear congressional intent is in accord with the principles governing the basic question of the availability of judicial review.

1. Congress contemplated that traditional declaratory judgment and injunction remedies would be available to challenge FDA regulations

The Court of Appeals ignored the express declaration in Section 701(f)(6) of the Act that *"the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."* (Emphasis added). Thus, even as to regulations made reviewable under Section 701(f), the judicial review provisions of the Act are stated to be nonexclusive. It can hardly be said, as the Court of Appeals held, that these judicial review provisions—stated to be in addition to other available remedies—operate to preclude review of regulations not covered by these provisions.

As has been noted, the Court of Appeals for the Second Circuit has rejected the Third Circuit's determination in this case that Congress intended to foreclose relief under the APA and the Declaratory Judgment Act with respect to FDA action not made reviewable under Section 701(f)(1) of the Food, Drug, and Cosmetic Act. The Second Circuit, in an opinion by Judge Friendly, relied on the clear statement in Section 701(f)(6), quoted above, and, in addition, pointed to legislative history as indicating that Congress had no intention of limiting review of actions not made specifically reviewable under the Food, Drug, and Cosmetic Act. This legislative history demonstrates that the contrary view of the Third Circuit in this case cannot be supported. It confirms the nonexclusive nature of the judicial review provisions of the Act and shows that Congress recognized that traditional equitable remedies and declaratory judgments would be available to provide relief against any FDA action, where relief would otherwise be appropriate, despite the specific review provisions in Section 701(f) of the Act.

As reported by the House Interstate and Foreign Commerce Committee, Section 701 of the bill enacted as the Food and Drug Act of 1938 had the same structure that it has today.[15] Section 701(a) of the bill granted "the authority to promulgate regulations for the efficient enforcement of this Act." S. 5, 75th Cong., 3d Sess. (1938). Section 701(e) of the bill set forth the procedure to be followed in formulating regulations under certain specified

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[15]Because the bill as reported by the Conference Committee, and as enacted, was "substantially the same as" the bill as passed by the House, see H. R. Rep. No. 2716, 75th Cong., 3d Sess. 22 (1938), the House consideration of the judicial review provisions is particularly pertinent. There is nothing to indicate that the Senate had a different understanding as to the nonexclusive nature of these judicial review provisions.

sections of the Act. And, Section 701(f) of the bill provided for judicial review of "any order under subsection (e)" and specified that "the remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law." (Compare the corresponding provisions of the Act, printed in the Appendix hereto.)

The House Report states explicitly that the "other remedies provided by law" may include equity and declaratory judgment proceedings:

> "There is also saved as a method to review a regulation placed in effect by the Secretary whatever rights exist to initiate a historical proceeding in equity to enjoin the enforcement of the regulation and whatever rights exist to initiate a declaratory judgment proceeding." H. R. Rep. No. 2139, 75th Cong., 3d Sess. 11 (1938).[16]

The Report of the Committee minority was in accord. The minority stated that the method of review provided in Section 701(f)

> "is in addition to, and not in substitution for, other methods of review provided by law, such as equity proceedings and proceedings under the Declaratory Judgment Act." H. R. Rep. No. 2139, pt. 2, 75th Cong., 3d Sess. 1 (1938).

The minority went on to criticize the judicial review provisions as going beyond existing law and being unduly protective of industry. This criticism was also made in a

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[16]In connection with this statement in the House Report, it should be noted that in at least one case an injunction was issued against the enforcement of a regulation issued under the 1906 Food and Drug Act even though that Act contained no provision for judicial review of regulations. Morgan v. Nolan, 3 F. Supp. 143 (S. D. Ind. 1933), *aff'd*, 69 F. 2d 471 (7th Cir. 1934).

memorandum prepared by the Department of Justice which was made public during the House debate on the bill. The Justice Department objected to the judicial review provisions of the bill on the ground that they permitted suits in courts other than the District Court for the District of Columbia, the jurisdiction where, in the absence of any specific judicial review provision, actions would have to be instituted. The Justice Department then stated its legal conclusion:

> "[T]he entire subsection [701(f)] is really unnecessary, because even without any express provision in the bill for court review, any citizen aggrieved by any order of the Secretary, who contends that the order is invalid, may test the legality of the order by bringing an injunction suit against the Secretary, or the head of the Bureau, under the general equity powers of the court." 83 Cong. Rec. 7892 (1938).[17]

[17]This same point—that judicial review was available even absent a specific provision for judicial review in the Act—was made strongly in a House Report during a previous Congress. The House Committee had deleted from a Senate-passed bill a provision for judicial review of regulations because the Committee felt that the existing judicial remedies were sufficient. In language particularly apposite to the issue involved here, the Committee explained:

> "The committee felt that there was no reason to add to the existing remedies which are applicable in the case of administrative action under the many other acts passed by Congress. There is always an appropriate remedy in equity in cases where an administrative officer has exceeded his authority and there is no adequate remedy of law, and furthermore the committee is of the opinion that ample protection is given by the so-called Declaratory Judgments Act enacted on June 14, 1934. . . . Insofar as the court would, under the Senate bill, have been empowered to give relief in case a regulation or an act of the Secretary was unreasonable, arbitrary, or capricious, or not in accordance with law, this is merely the ordinary principle which the court applies in cases where an administrative official has exceeded his authority, and a person affected by an administrative official's action may always, whether in a criminal proceeding, equity proceeding, or any other proceeding, raise these issues. . . .

Representative Mapes offered an amendment to Section 701(f) which, among other things, would have authorized review in the Courts of Appeals instead of in the District Courts. See 83 Cong. Rec. 7891 (1938). Representative Mapes echoed the views of the Department of Justice:

> "[U]nder existing law any individual may go into the district court in which he resides for the purpose of obtaining an injunction against any order of the Food and Drug Administration that applies to him, that is arbitrary, capricious, unreasonable, or contrary to law, and that will cause him irreparable damage. *No one proposes to take that right away from anyone.*" *Id.* at 7893. (Emphasis added.)

He was questioned by Representative Voorhis:

> "MR. VOORHIS. What about injunctions under the gentleman's amendment?
> "MR. MAPES. The injunction matter is outside of both of these provisions. *The injunction remedy by any aggrieved person is had without reference to the provisions in the bill or to my amendment.*" *Id.* at 7894. (Emphasis added.)

Although Representative Mapes' amendment was defeated, *id.* at 7898, a provision for review in the Court of Appeals was contained in the bill as reported by the Conference Committee and as enacted. The Conference Committee specifically noted that

> "the provision of the House amendment under which the remedies provided for are in addition to, and not in substitution for, other legal remedies, is

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The remedy furnished [by the Declaratory Judgment Act] seems to be peculiarly adapted to cases where the interests and rights of parties are affected by the acts of administrative officials. Prof. Edwin Borchard, of the Yale University School of Law, a recognized authority on this subject, stated in an article appearing in the Law Week that it is in this field that the act will have its greatest usefulness." H. R. Rep. No. 2755, 74th Cong., 2d Sess. 8-9 (1936).

retained." H. R. Rep. No. 2716, 75th Cong., 3d Sess. 25 (1938).

The legislative history thus conclusively demonstrates that Congress specifically contemplated that traditional remedies would be available to challenge any FDA action. The provision for judicial review of certain specified regulations was intended to constitute an additional remedy in the case of the specified regulations—regulations dealing with technical and scientific issues, and to be adopted after evidentiary hearings—and is not an implied preclusion of the review of other FDA action. The Declaratory Judgment Act and the APA are available to review the regulations at issue here and, as has been shown, the requirements of those statutes were met in this case. The Court of Appeals' decision barring the courts to petitioners was in error and contrary to the intent of Congress.

2. This clear congressional intent is consistent with the principles governing the availability of judicial review

The Court of Appeals did not even mention the express declaration in Section 701(f)(6) of the Act that the judicial review provisions of the Act are nonexclusive. Nor did the Court refer at all to any legislative history as bearing on the availability of judicial review. The Court held baldly that review of the regulations at issue here was precluded solely because other action taken by the Food and Drug Administration is made specifically reviewable under the Food and Drug Act. This holding is demonstrably erroneous in light of the clear and unambiguous legislative history which has already been discussed. Moreover, this ruling of the Court of Appeals is in clear conflict with decisions of this Court. These decisions, even prior to the enactment of the Administrative Procedure Act, demonstrate that the mere fact that certain agency action is made specif-

ically reviewable does not preclude, by negative implication, the reviewability of other action. *Shields* v. *Utah Idaho Central R. R.*, 305 U. S. 177 (1938); *Stark* v. *Wickard*, 321 U. S. 288 (1944). With the enactment of the APA, it is untenable even to argue, as the Court of Appeals held, that review of the regulations at issue here is unavailable solely because other regulations are made specifically reviewable.

Shields involved an Interstate Commerce Commission determination that the railroad was not exempt from the requirements of the Railway Labor Act. The Court had previously held in *Shannahan* v. *United States*, 303 U. S. 596 (1938), that such a determination was not an "order" reviewable under the Urgent Deficiencies Act. The Court held in *Shields*, however, that the determination was reviewable under the general equity jurisdiction of the District Courts. In other words, the fact that certain ICC action was reviewable under the Urgent Deficiencies Act did not by negative implication preclude review of other action under general equity jurisdiction.

Stark v. *Wickard* was an action brought by milk producers to enjoin the implementation of certain provisions of an order of the Secretary of Agriculture issued under the Agricultural Marketing Agreement Act. The Act provided for review of other orders and made no provision for review of the type of order there involved. The Court nevertheless held—over the objection of Mr. Justice Frankfurter in dissent that the specific provision for review of some orders demonstrated that other orders were not reviewable (321 U. S. at 318-19)—that the order was reviewable under the general equity jurisdiction of the District Courts. Indeed, the Court, after noting that provision was made in the Act for the review of some orders, stated:

> "With this recognition by Congress of the applicability of judicial review in this field, it is not to be

> lightly assumed that the silence of the statute bars from the courts an otherwise justiciable issue. . . ." 321 U. S. at 309.

There can be no doubt that the *Shields* and *Stark* v. *Wickard* approach was confirmed and strengthened with the enactment of the Administrative Procedure Act in 1946. This Court has referred to "the generous review provisions" of the APA and has stated that they granted "an expanded right of review" and that the APA "is to be given a 'hospitable' interpretation." *Shaughnessy* v. *Pedreiro*, 349 U. S. 48, 51 (1955); see *Brownell* v. *Tom We Shung*, 352 U. S. 180, 185 (1956). In light of the "broadly remedial provisions" of the APA, the Court has stressed that it will require "clear and convincing evidence" of congressional intent before it will hold that judicial review of administrative action is unavailable. *Rusk* v. *Cort*, 369 U. S. 367, 379-80 (1962). *Heikkila* v. *Barber*, 345 U. S. 229 (1953), in which this Court reviewed the legislative history of the APA, shows that in this case the mere fact that some FDA regulations were made specifically reviewable is not "clear and convincing evidence" of congressional intent to preclude review of other regulations. In *Heikkila* the Court quoted with approval the statement in the House Report on the APA:

> " 'To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.' " 345 U. S. at 232.

The Court indicated the necessity for a close examination of the purpose and history as well as the text of a statute in order to determine whether Congress intended to prevent the courts from affording relief to those adversely affected

by administrative action. The text of a statute, even where it looks toward the unavailability of review, is not decisive:

> "Mere failure to provide for judicial intervention is not conclusive; neither is the presence of language which appears to bar it." 345 U. S. at 233, citing, *inter alia*, *Stark* v. *Wickard*.

The Court of Appeals here, however,—with an extremely superficial examination of the text of the statute and with no consideration of its purpose or legislative history—held that Congress intended, by implication, to preclude review of the type of regulations involved in this case because it specified the availability of review for other regulations. If this implication is supportable on this basis in this case, it necessarily means that no order of any administrative agency is reviewable under the Declaratory Judgment Act and the APA where the agency's governing statute specifically authorizes the review of certain other orders. This cannot be, and is not, correct. The Court of Appeals' decision cannot square with *Shields* and *Stark* v. *Wickard;* it is also contrary to, *e.g.*, *Leedom* v. *Kyne,* 358 U. S. 184 (1958) (that certain types of NLRB orders were made reviewable in the Courts of Appeals did not by negative implication preclude equitable District Court action to review other types of NLRB orders), and *Rusk* v. *Cort, supra* (statutory authorization of review by certain class of persons did not by negative implication preclude review by other persons). See also, *e.g.*, *Elmo Division of Drive-X Co.* v. *Dixon,* 348 F. 2d 342, 343 (D. C. Cir. 1965); *Deering Milliken, Inc.* v. *Johnston,* 295 F. 2d 856 (4th Cir. 1961). As pointed out by Professor Jaffe:

> "The mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others. The right to review is too impor-

tant to be excluded on such slender and indeterminate evidence of legislative intent." Jaffe, *Judicial Control of Administrative Action* 357 (1965).

II

PETITIONERS NOT INCORPORATED IN DELAWARE ARE PROPERLY PARTIES PLAINTIFF ALONG WITH PETITIONERS INCORPORATED IN DELAWARE AS TO WHOM VENUE IS ADMITTEDLY PROPER

In this proceeding involving a basic question of importance to the entire prescription drug industry, suit was instituted by thirty-seven representative manufacturers and by the Pharmaceutical Manufacturers Association ("PMA"), the association of which these companies and more than 100 other prescription drug manufacturers are members. Venue in the District Court for the District of Delaware was admittedly proper under the governing venue provision, 28 U. S. C. § 1391(e)(4) (Appendix, p. 3a), for the twelve petitioners, including the PMA, incorporated in Delaware. Consequently, the basic issue of these petitioners' right to an adjudication of the legality of the regulations is before this Court, regardless of the disposition of the venue issue involving other plaintiffs not incorporated in Delaware.

The venue question as to petitioners not incorporated in Delaware was decided by the Court of Appeals in case No. 15054 and was taken by this Court under its grant of certiorari. A basic question of considerable importance to the administration of justice in the lower Federal courts is involved. It plainly merits resolution by this Court now. The restrictive holdings below contravene the purpose of the liberalizing venue provision and would preclude plaintiffs with a proper interest from being parties in litigation affecting their rights.

Under the venue statute applicable to this action, 28 U. S. C. § 1391(e)(4), venue is properly laid "in any judicial district in which . . . the plaintiff resides. . . ." There is no dispute that, under this section, a corporate plaintiff "resides" at least in its state of incorporation. The District Court determined that a corporate plaintiff "resides" only in its state of incorporation (R. 43-46), and the Court of Appeals in its case No. 15054 affirmed the District Court's dismissal of the Complaint as to those petitioners not incorporated in Delaware (R. 64-65).

Petitioners believe that the provisions of Section 1391 and the congressional purpose in broadening this section, and in particular in amending this section in 1962 to add subsection (e)(4) which controls this action, show that venue was also proper for those petitioners not incorporated in Delaware and that the contrary conclusion by the courts below was in error.

A. Prior to the codification of the Judicial Code in 1948, for venue purposes a corporation was deemed a resident only of its state of incorporation. *E.g., Suttle* v. *Reich Bros. Constr. Co.*, 333 U. S. 163 (1948). This was changed in 1948 by the adoption of Section 1391(c) of the Judicial Code, which reads:

> "A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, *and such judicial district shall be regarded as the residence of such corporation for venue purposes.*" (Emphasis added.)

Under this section, it is clear that a corporate defendant now "resides" in every district in which it is either incorporated, licensed to do business, or doing business. The issue is whether this section redefined corporate residence for corporate plaintiffs as well as for corporate defendants.

Section 1391(a) provides that an action in which Federal jurisdiction is based solely on diversity of citizenship

may be brought in the judicial district in which either the plaintiffs or the defendants "reside." In this situation, a conflict soon developed among the courts and the commentators as to whether the definition of corporate residence in Section 1391(c) applied where venue was sought to be based on the residence of corporate plaintiffs. The conflicting cases and commentary are cited in the District Court's opinion (R. 44 nn. 2, 3).

The fact that this conflict developed certainly demonstrates that the statutory language can be read either way—as limited to corporate defendants or as encompassing corporate plaintiffs as well. Nor is the Reviser's Note to this section of any help. See 1 Moore, *Federal Practice* ¶ 0.142[5.-3], at 1489 n. 1 (1964). There is, thus, no authoritative source which can be looked to for the answer. Petitioners urge that this Court follow the reasoning of those courts which have held that Section 1391(c) applies to corporate plaintiffs as well as corporate defendants. This reasoning is spelled out by Judge Ryan in *Freiday* v. *Coudin*, 83 F. Supp. 516, 517-18 (S. D. N. Y.), *appeal dismissed by consent*, 177 F. 2d 1020 (2d Cir. 1949):

> "To give full effect to the words 'and such judicial district shall be regarded as the residence of such corporation for venue purposes' one must conclude that they refer to both plaintiff and defendant corporations. To conclude otherwise one would have to attribute to Congress the anomalous intent to define the residence of corporate defendants but not that of corporate plaintiffs. Under such interpretation, there would be nothing in the Code defining the residence of corporate plaintiffs. . . . Furthermore, corporations would be amenable to suit in jurisdictions in which they were licensed to do business or were doing business, but they could not sue as plaintiffs [under 28 U. S. C. § 1391(a)] in those very same districts unless all defendants were residents of that district."

It has not been suggested that the result reached in cases consistent with *Freiday* v. *Cowdin* is in any way undesirable or without logical support. See 1 Moore, *supra* at 1503. After all, a liberal reading of Section 1391(c) in diversity cases—the situation in which the issue is presented—is indicated by the fact that such cases are already governed by a more liberal venue requirement than are "Federal question" cases.[18] Nor can there be any legitimate fear, in view of the necessity for service of process on the defendant, that the reading of Section 1391(c) urged by petitioners would in any way prejudice the defendants in actions brought by corporate plaintiffs.

The District Court here, however, rejected the reasoning of *Freiday* v. *Cowdin* and its companion cases, and the Court of Appeals affirmed per curiam. The District Court, relying on Professor Moore, advanced two reasons for its action, neither of which, it is believed, affects the persuasiveness of the *Freiday* v. *Cowdin* reasoning. First, the District Court noted that Professor Moore had concluded that effect could be given to the second clause of Section 1391(c) even if that clause were not held applicable to corporate plaintiffs.[19] This must, however, be conceded to be a very limited and technical effect; as Chief Judge Ryan stated in *Freiday* v. *Cowdin, supra,* "to give *full effect* to the words [of the second clause of Section 1391(c)] one must conclude that they refer to both plaintiff and defendant corporations." (Emphasis added.) Second, the District Court was im-

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[18] Under § 1391(a), in diversity cases venue is based on either the plaintiff's or the defendant's residence; in "Federal question" cases venue is proper under § 1391(b) only in the district in which the defendant resides.

[19] Professor Moore states:

> "This [second] clause serves a purpose in laying venue, in a transitory action, in a defendant's district where there are multiple defendants residing in different districts of the same state; and also in the case where defendants reside in different divisions of the same district or different districts in the same state." 1 Moore, *supra* at 1503.

pressed by the argument that Congress did not intend to effect what the Court concluded would be a "far-reaching change" (R. 46) were Section 1391(c) applicable to corporate plaintiffs.[20] Even Professor Moore, however, does not believe that this argument carries much weight, 1 Moore, *supra* at 1503; indeed, he states explicitly:

> "When 28 U. S. C. § 1391(c) was enacted it represented a marked change in the former statutes and some substantial change in the practice." 1 Moore, *supra* at 1493.

There are thus no obstacles to the adoption of a good sense, rational construction of Section 1391(c)—that in cases governed by the general venue provisions of Section 1391, the definition of corporate residence in Section 1391 (c) applies to corporate plaintiffs as well as corporate defendants. This result is called for both by the "liberalizing purpose underlying" the enactment of Section 1391(c)—"to bring venue law in tune with modern concepts of corporate operations"—and by the "generality of . . . language" used in Section 1391(c). *Pure Oil Co.* v. *Suarez*, 384 U. S. 202, 204-05 (1966).

B. In any event, even if the definition of corporate residence in Section 1391(c) does not apply to corporate plaintiffs in all cases in which venue is governed by Section 1391, the reasons for the enactment of Section 1391(e)(4) require that this definition apply in cases falling within that section.

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[20] The District Court apparently concluded (R. 46) that Congress, in enacting § 1391(c), intended to do no more than codify the doctrine announced by this Court in Neirbo Co. v. Bethlehem Shipbuilding Corp., 308 U. S. 165 (1939), that a corporation waives its venue privilege by becoming licensed to do business in a state. As Professor Moore points out, however, § 1391(c) is broader than the *Neirbo* doctrine. 1 Moore, *supra* at 1493.

There can be no dispute that in enacting Section 1391(e) in 1962, Congress intended to broaden significantly the venue provisions in actions instituted against Federal officials.[21] Thus, even if as the District Court determined, Congress did not in 1948 intend what that Court concluded would be a "far-reaching" change were Section 1391(c) applicable to corporate plaintiffs in, for example, the typical diversity case, this conclusion does not bear on the proper interpretation of Section 1391(e). Whatever may have been the situation in 1948, the focus must be on the action of Congress in 1962, and the issue here should be decided so as best to effectuate the purpose of Congress in enacting Section 1391(e) in 1962.

The decisions below, when viewed in this light, are erroneous and should be reversed. These decisions are not consistent with the policy of Congress to give paramount consideration to the needs of private litigants, who often carry on their businesses far from their states of incorporation, and to lessen the burden on the District Court for the District of Columbia.[22] Specifically, where there are a

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[21] "The bill . . . is intended to facilitate review by the Federal courts of administrative actions. To attain this end, the bill . . . broadens the venue provisions of title 28 of the United States Code. . . ." S. Rep. No. 1992, 87th Cong., 2d Sess. 2 (1962); see H. R. Rep. No. 536, 87th Cong., 1st Sess. 1-2 (1961).

[22] "The Government official is defended by the Department of Justice whether the action is brought in the District of Columbia or in any other district. U. S. attorneys are present in every judicial district. Requiring the Government to defend Government officials and agencies in places other than Washington would not appear to be a burdensome imposition.

"On the other hand, where a citizen lives thousands of miles from Washington, . . . to require that the action be brought in Washington is to tailor our judicial processes to the convenience of the Government rather than to provide readily available, inexpensive judicial remedies for the citizen who is aggrieved by the workings of Government.

* * *

"[T]he present venue provision results in a concentration of these actions in the District Court for the District of Colum-

number of plaintiffs, as in the instant action, the effect of the decisions below is to require plaintiffs to bring a multiplicity of suits in the Federal courts of their states of incorporation or a consolidated suit in the District of Columbia.

On the other hand, the interpretation of Section 1391 (e) urged by the petitioners is in accord with the legislative history of Section 1391(e) and carries out the purpose of Congress in enacting that section. The difficulties, noted above, which are presented by the restrictive view of Section 1391(e) adopted by the courts below are eliminated by incorporating into the word "resides" in Section 1391(e)(4) the definition of corporate residence in Section 1391(c). When this is done, it is clear that venue is proper as to each petitioner in this case which is incorporated in Delaware, licensed to do business in Delaware, or doing business in Delaware. Since the respondents showed only that a number of petitioners were not incorporated in Delaware, the courts below erred in dismissing those petitioners from this action.

CONCLUSION

The judgments of the Court of Appeals should be reversed and the case remanded to the Court of Appeals for a determination of the substantive issue in this case—the legality of the respondents' regulations as to which there

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bia, a court which is already heavily burdened. Court congestion is increased and substantial delays are incurred. The broadened venue provided in this bill will assist in achieving prompt administration of justice by making it possible to bring these actions in courts throughout the country, many of which are not nearly as burdened as the District Court for the District of Columbia." S. Rep. No. 1992, 87th Cong., 2d Sess. 3 (1962); see H. R. Rep. No. 536, 87th Cong., 1st Sess. 3 (1961).

has been a basic dispute since their promulgation in 1963. The public interest and the interests of all those affected by the issue—the Food and Drug Administration, all the petitioners and every other company in the prescription drug industry, as well as the medical profession—will be served by a resolution of the merits of this controversy. Plainly put, it is truly shameful that the resources of the petitioners and of the agencies of the United States Government, and the time of busy Federal courts, have had to be expended for several years in dealing with procedural skirmishes designed by respondents to avoid review by the courts of enforcement regulations which respondents formally promulgated and as to which there is a well-grounded, basic claim of illegality.

The issue of the validity of the regulations was squarely presented on the record for decision by the Court of Appeals. Regardless of the disposition of the venue question as to the petitioners not incorporated in Delaware, there are twelve petitioners as to whom venue is concededly proper and who are entitled to an adjudication. There is no controverted issue of fact, and the regulations would adversely affect an entire industry which has been earnestly seeking since 1963 consideration of the merits of the issue. Both the Declaratory Judgment Act and the Administrative Procedure Act called for the Court of Appeals to have decided the merits. Had the Court of Appeals given effect to these basic jurisdictional statutes and to the principles enunciated by this Court in its controlling

decisions, the merits would have been reached and decided. The Court of Appeals should be directed to do so now.

Respectfully submitted,

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APPENDIX

I. Statutes

Declaratory Judgment Act, 28 U. S. C. §§ 2201-02 (1964):

"§ 2201. Creation of remedy.

"In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

"§ 2202. Further relief.

"Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment."

Administrative Procedure Act, § 10, 60 Stat. 243 (1946), 5 U. S. C. § 1009 (1964):

"Sec. 10. Except so far as (1) statutes preclude judicial review or (2) agency action is by law committed to agency discretion—

"(a) Right of review.—Any person suffering legal wrong because of any agency action, or adversely affected or aggrieved by such action within the meaning of any relevant statute, shall be entitled to judicial review thereof.

"(b) Form and venue of action.—The form of proceeding for judicial review shall be any special statutory review proceeding relevant to the subject matter in any court specified by statute or, in the

absence or inadequacy thereof, any applicable form of legal action (including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus) in any court of competent jurisdiction. Agency action shall be subject to judicial review in civil or criminal proceedings for judicial enforcement except to the extent that prior, adequate, and exclusive opportunity for such review is provided by law.

"(c) Reviewable acts.—Every agency action made reviewable by statute and every final agency action for which there is no other adequate remedy in any court shall be subject to judicial review. Any preliminary, procedural, or intermediate agency action or ruling not directly reviewable shall be subject to review upon the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final shall be final for the purposes of this subsection whether or not there has been presented or determined any application for a declaratory order, for any form of reconsideration, or (unless the agency otherwise requires by rule and provides that the action meanwhile shall be inoperative) for an appeal to superior agency authority.

* * *

"(e) Scope of review.—So far as necessary to decision and where presented the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of any agency action. It shall . . . (B) hold unlawful and set aside agency action, findings, and conclusions found to be (1) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . [or] (3) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. . . ."

Judicial Code, § 1391, 28 U. S. C. § 1391 (1964):

"§ 1391. Venue generally.

* * *

"(c) A corporation may be sued in any judicial district in which it is incorporated or licensed to do business or is doing business, and such judicial district shall be regarded as the residence of such corporation for venue purposes.

* * *

"(e) A civil action in which each defendant is an officer or employee of the United States or any agency thereof acting in his official capacity or under color of legal authority, or an agency of the United States, may, except as otherwise provided by law, be brought in any judicial district in which: (1) a defendant in the action resides, or (2) the cause of action arose, or (3) any real property involved in the action is situated, or (4) the plaintiff resides if no real property is involved in the action.

"The summons and complaint in such an action shall be served as provided by the Federal Rules of Civil Procedure except that the delivery of the summons and complaint to the officer or agency as required by the rules may be made by certified mail beyond the territorial limits of the district in which the action is brought."

Federal Food, Drug, and Cosmetic Act, § 502(e)(1), 52 Stat. 1050 (1938), as amended by § 112(a) of the Drug Amendments of 1962, 76 Stat. 790, 21 U. S. C. § 352(e)(1) (1964):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(e)(1) If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or

the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient . . . and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient: *Provided*, That to the extent that compliance with the requirements of clause (A) (ii) or clause (B) of this subparagraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary."

Federal Food, Drug, and Cosmetic Act, § 502(n), added by § 131(a) of the Drug Amendments of 1962, 76 Stat. 791, 21 U. S. C. § 352(n) (1964):

"Sec. 502. A drug or device shall be deemed to be misbranded—

* * *

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act. . . ."

Federal Food, Drug, and Cosmetic Act, § 701, 52 Stat. 1055 (1938), as amended, 21 U. S. C. § 371 (1964):

"(a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is vested in the Secretary.

* * *

"(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406, 501(b), or 502(d) or (h) of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

"(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specify-

ing those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

"(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

"(f)(1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. . . .

* * *

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law."

II. Regulations

Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, §§ 1.104(g), 1.105(b), 28 Fed. Reg. 6375, 6376 (1963), 21 C. F. R. §§ 1.104(g), 1.105(b) (1965):

"§ 1.104 Drugs; statement of ingredients.

* * *

"(g)(1) If the label or labeling of a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features.

"§ 1.105 Prescription-drug advertisements.

* * *

"(b)(1) If an advertisement for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation, shall accompany each appearance of such proprietary name or designation. The established name shall be placed in direct conjunction

with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as 'brand of,' preceding the established name, or by brackets surrounding the established name.

"(2) The established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined, and the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features."